**The 35 U.S.C. §103 Rejection**

Claims 1, 3-6, and 8-40 were rejected under 35 U.S.C. §103(a) as obvious over Halperin et al. (U.S. Patent No. 5,564,434) in view of Anderson et al. (U.S. Patent No. 4,552,432). Applicants respectfully traverse this rejection and the assertions made in support of it.

In support of this obviousness rejection it is asserted that one of ordinary skill in the art would have substituted the cable of Anderson et al. for the coiled inner conductor 16 of Halperin. Applicants respectfully submit, however, that the asserted obviousness rejection of claims 1, 3-6, and 8-40 does not meet the requirements for a *prima facie* case of obviousness.

Among the reasons for Applicants' position that a *prima facie* case of obviousness has not been established is that the proposed modification would render the medical electrical lead of Halperin unsuitable for its intended purpose. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *See, e.g.,,* MPEP § 2143.01(V) (*citing In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

The inner coiled conductor 16 of Halperin, in addition to carrying electrical signals, also defines a stylet receiving lumen as discussed in the following excerpt from column 7 of Halperin:

> pressure sensor module **20**. A stylet receiving lumen is formed within the inner coiled wire lead conductor **16** and extends to the connection with the sensor module **20**.
>
> The in-line connector assembly **30** includes an inner connector pin **36** having a styler receiving, pin lumen **38** and is attached to the proximal end of the inner coiled wire conductor **16** to align the pin lumen **38** with the stylet receiving lumen of the inner coiled wire conductor **16**. An

As discussed in the excerpt reproduced above, the stylet receiving lumen within the conductor 16 is aligned with the pin lumen 38 in the connector assembly 30. These features can be seen in Figures 2 and 3 of Halperin as reproduced below:

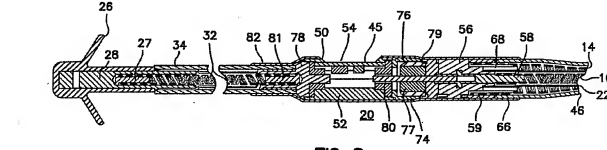



FIG. 2

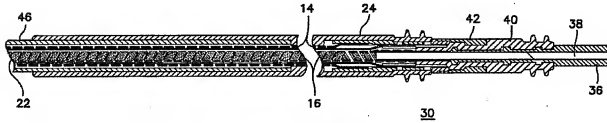
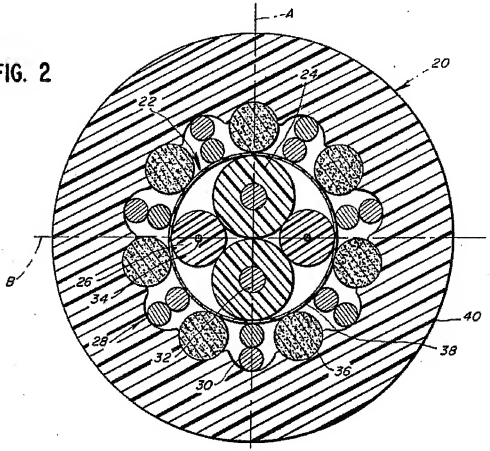



FIG. 3

Applicants respectfully submit that, if the coiled conductor 16 of Halperin were replaced by the cable of Anderson et al. as proposed in support of this obviousness rejection, the conductor 16 would not include a stylet receiving lumen and would, therefore, be unable to accept a stylet for proper use of the medical electrical lead. No stylet receiving lumen would be provided because the construction of the cable taught in Anderson et al. includes no lumen as seen in, e.g., Figure 2 of Anderson et al. as reproduced below.

FIG. 2




In other words, the proposed modification to replace the coiled conductor 16 of Halperin (which includes a stylet receiving lumen) with the cable conductor of Anderson et al. would yield a medical electrical lead with no stylet receiving lumen, thereby rendering the medical electrical lead of Halperin et al. unsuitable for its intended purpose.

Furthermore, the cable of Anderson et al. is described as a "hybrid cable" that includes conductors for both optical and electrical connections. In particular, the central section 22 of the cable (including at least one optical conductor 26 and "strength members" 24) is not electrically connected to any other components. *See, e.g., Anderson et al.*, column 2, line 65 to column 3, line 14. In fact, the central section 22 of the cable includes only components for optical

connections and components to increase the strength of the cable (to protect the lower strength optical conductor 26).

In contrast, independent claims 1 and 20 recite that both the outer coil conductor and the inner cable conductor are electrically connected to the sensor capsule.

As a result, Applicants respectfully submit that one of ordinary skill in the art would not be motivated to use the teachings of Anderson et al. to modify the medical electrical lead of Halperin et al. because to do so would require a change in the function of the cables taught in Anderson et al. "A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art." M.P.E.P. §2143(A) (citing *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1395 (2007)) (emphasis added). In view of the above, Applicants respectfully submit that modifying the function of the cables taught by Anderson et al. is impermissible to establish a *prima facie* case of obviousness.

In response to these arguments as presented by Applicants in the previous paper, it was asserted in the "Response to Arguments" section of the Office Action that "the test [for obviousness] is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The examiner relies on Anderson et al. for the teachings of multiple wire strands disposed around multiple wire strands, and not the bodily incorporation of both structures." *Office Action*, page 2 (June 23, 2011).

Applicants respectfully note, however, that despite the caselaw cited by the Examiner, the standards for assessing whether or not a *prima facie* case of obviousness has been established do still require that the proposed combination not render the prior art being modified unsatisfactory for its intended purpose. *See, e.g.,,* MPEP § 2143.01(V) (*citing In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). In addition, the cited caselaw also does not negate the

requirement that the claimed elements have no change in function when combined as proposed in support of an obviousness rejection. "A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art." M.P.E.P. §2143(A) (citing *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1395 (2007)) (emphasis added).

Although Anderson et al. does teach multiple wire strands wrapped around a core, that construction cannot accommodate a stylet lumen. No reasoning has been provided in support of this rejection as to how or why one of ordinary skill in the art would modify the core of Anderson et al. to accommodate a stylet lumen as taught in the leads of Halperin et al. Nor has any reasoning been provided as to why one of ordinary skill in the art would have replaced the optical conductors in the core of Anderson et al. with electrical conductors.

If, in the absence of any explicit teachings in Anderson et al. that its core could be modified to accommodate a sylet lumen and to replace the optical conductors with electrical conductors, it is asserted that somehow one of ordinary skill in the art would understand that Anderson et al. inherently teaches such a construction, then Applicants respectfully submit that the requirements for a rejection based on inherency have not been met.

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112(IV), p. 2100-47, 8th Ed., Rev. 6, (Sept. 2007) (emphasis in original) (*citing In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993)). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Id.* at p. 2100-48 (citing *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)).

In the present rejection, no basis in fact or technical reasoning has been provided to show how or why one of ordinary skill in the art would necessarily understand that Anderson et al. teaches or suggests that using the Anderson et al. core in the leads disclosed by Halperin et al. could "provide the predictable results of...protecting the inner coil and stylet lumen" (emphasis added) as asserted in support of this rejection. This is particularly so in the present case because Anderson et al. does not, itself, include a stylet lumen that would need to be protected. Rather, Anderson et al. teaches, as discussed above, only constructions that preclude the existence of stylet lumen. Furthermore, no basis in fact or technical reasoning has been provided to show why or how one of ordinary skill would replace the optical conductors of the Anderson et al. core with electrical conductors.

In addition to the comments provided above, Applicants also disagree with the assertions made in support of the rejection of claims 35-36 and 38-39, i.e., that "the examiner considers the stylet to be a 'center strand' wherein 'the multiple strands of the inner layer are wound around the center strand." *Office Action*, page 5 (June 23, 2011). The stylet of Halperin et al. is not part of the disclosed inner coiled wire lead 16 of Halperin et al. It is, rather, a transitory object that is provided to facilitate advancement of the lead, followed by its removal. Further, the asserted "cable conductor" in any such construction does not include both inner and outer layers as recited in independent claims 1 and 20, from which claims 35-36 and 38-39 depend.

For at least the reasons presented herein, Applicants respectfully submit that the combination of Halperin et al. in view of Anderson et al. does not support a *prima facie* case of obviousness. Reconsideration and withdrawal of the obviousness rejection of claims 1, 3-6, and 8-40 are, therefore, respectfully requested.

## Summary

It is respectfully submitted that claims 1, 3-6, and 8-40 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
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The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 C.F.R. §1.6(a)(4) to the Patent and Trademark Office addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23rd day of September, 2011.

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